IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/510,562	Confirmation No.: 3061
Applicant	:	Gerard M. Housey	
Filed	:	February 22, 2000	
TC/A.U.	:	1636	
Examiner	:	Guzo, D.	
Docket No.	:	395/35	
Customer No.	:	23838	

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration of James D. Griffin, M.D. Under 37 C.F.R. § 1.132

SIR:

I, James D. Griffin, M.D., hereby declare and state as follows:

1. I am a Professor of Medicine at Harvard Medical School. I am Chairman of the Department of Medical Oncology at the Dana-Farber Cancer Institute as well Professor of Medicine at Harvard Medical School. I am the Director of the Leukemia Program at the Dana-Farber/Harvard Cancer Center. I also serve on the External Advisory Board of Johns Hopkins Hospital Cancer Center and the Lombardi Cancer Center of Georgetown University Medical Center. I received a Bachelor of Arts degree and a Master of Medical Science degree from Brown University in 1970 and 1972 respectively, and a Doctor of Medicine degree from Harvard Medical School in 1974. A copy of my *curriculum vitae* has been designated Exhibit A.

2. At various times from 1984 to the present, I have been on the Editorial Boards of *Blood*; *Leukemia Research*; *Experimental Hematology*; *Leukemia*; and *British Journal of Hematology*, have been an Associate Editor of *Hematological Oncology* and *Blood* and have served as Editor-in-Chief of *Blood*. Most of the research I have performed in my more than

served as Editor-in-Chief of *Blood*. Most of the research I have performed in my more than twenty five years in medicine has involved the general areas of hematology and oncology, including the study of regulation of hematopoiesis, the biology of myeloid leukemias, and the function of hematopoetic growth factors. In the course of my career, I have authored or coauthored numerous articles that deal specifically with regulation of cellular biological functions, including aberrant expression of cellular proteins and interactions of cell surface receptors and their ligands.

3. I have provided expert testimony and declarations for Housey Pharmaceuticals, Inc. in the past and have worked with Kenyon & Kenyon on other patent-related matters.

4. In my opinion, one of ordinary skill in the art relevant to this subject matter would have an advanced degree in a biomedical field of science, such as medicine, cell biology, molecular biology, immunology, or a related field, and at least one or two years of additional research experience.

5. Housey's invention is directed to a method of determining whether a substance is an inhibitor or activator of a particular protein. Prior to Housey, methods of finding modulators of cellular functions using different types of assays were known. Specification, page 1, lines 12-19. Such assays would necessarily find inhibitors or activators of proteins or other cellular components albeit in a non-specific manner because any substance (*i.e.*, any agent) which altered the function, *i.e.*, the phenotypic characteristic under examination, would be detected. For example, an agent which inhibits the growth properties of cells or which inhibits cellular growth "in any way" scores positive in a cell-based assay for colony formation in soft agar but has not necessarily targeted a protein of interest ("POI"). *Id.* at page 2, lines 8-10, 25-27; page 3, lines 9-12.

6. Housey's improvement over the prior art assays was to provide a method of screening using a cell-based assay to identify inhibitors or activators which are specific for a particular protein. Specification, page 3, line 31 to page 4, line 4. Housey's claimed method requires that the POI be overproduced in a test cell and, under appropriate culture conditions, that such expression leads to a change in a phenotypic characteristic of the test cell other than the level of the POI *per se* (relative to a control), *i.e.*, that production of the protein in the test cell evokes a responsive change in a phenotypic characteristic other than the level of the protein in the cell *per se*. It is this identified phenotypic response that is then used to search for inhibitors or activators of the POI.

7. The Housey method requires a specific type of change in a phenotypic characteristic of the cell. Housey requires that the changed phenotypic characteristic arise from activity of the protein as it functions in the cell and not from the mere presence of the protein in the cell. Without this feature, there could be no specificity in Housey's method of identifying substances which directly and specifically stimulate or inhibit the activity of a protein (the POI) by monitoring changes in a phenotypic characteristic in response to the substance.

8. The specific change in a phenotypic characteristic and the sensitivity of that phenotypic characteristic is dependent on the cell's production of the POI. According to the method, test cells are generated that stably overproduce the POI. Under appropriate growth conditions, the cells exhibit a "graded cellular response" to activators or inhibitors of the POI. Specification, page 4, lines 13-16; page 4, line 35 to page 5 line 2.

9. A graded cellular response is a phenotypic change exhibited by a cell which becomes greater with increasing expression of the POI. Specification, page 12, lines 22-28. For example, where an observable phenotypic change is growth in soft agar, there is a graded cellular response if a relatively low level of the POI results in relatively small changes in growth in soft

agar by modulators of the POI whereas a relatively high level of the POI results in relatively large changes in growth in soft agar by modulators of the POI. The phenotypic change is responsive to the level of the protein.

10. I am familiar with the Office Action mailed October 5, 2005, including the reasons set forth by the Examiner in support of his conclusion that the specification does not enable a person skilled in the art to which it pertains to practice the claimed invention because undue experimentation would be required in order to sort out whether a test agent is a direct inhibitor or activator or the POI or is exerting its effect on the observed phenotypic changes by some other (indirect) mechanism. Based on my knowledge of and experience in the cell biology field, I respectfully disagree based on the following.

11. Housey's specification teaches that a useful graded cellular response can be provided by stable overexpression of a POI. Housey's specification demonstrates that in the example where the POI is the β isoform of protein kinase C, inhibitors of protein kinase C reduce the phenotypic change in the cells in a graded manner. Using the same specialized phenotype, the specification also demonstrates that tamoxifen is a direct inhibitor of protein kinase C.

12. Housey's identification and use of a graded cellular response enables one of ordinary skill in the art to identify substances which are modulators of the POI that evokes the graded cellular response. This specific type of change in a phenotypic characteristic allows the identification of modulators that act directly on the POI instead of modulators that act on other cellular components.

13. One of ordinary skill in the art would be able to identify activators and inhibitors of a POI by the methods disclosed by Housey. Since the time of Housey's invention, stable overproduction of a POI has become an established means for distinguishing the effect of modulators of a POI on a phenotype from confounding effects of other cellular components.

14. The Examiner has cited certain references to illustrate the complex and unpredictable nature of signaling pathways and how use of phenotypic changes associated with expression of a target enzyme (POI) in a method for identifying direct inhibitors or activators of the POI can actually result in identification of agents which do not interact with the target but instead interact with another component of the cell. Whatever complexity and unpredictability is ascribed to other methods in the art that employ phenotypic changes in cells or seek to identify inhibitors or activators of a POI cannot be used to evaluate Housey's method because Housey's method is different from that art. In fact, Housey's method operates in the face of such complexities. One of ordinary skill would recognize the difference between Housey's invention and such methods. Further, one of ordinary skill with knowledge of Housey's invention, upon practicing the methods disclosed in the articles would not be misled into thinking that activators or inhibitors obtained by such methods were direct (specific) activators or inhibitors of the POI.

15. Hsiao et al., Mol. Cell. Biol., 1986, Vol. 6, No. 6, pp. 1943-1950 (Hsiao) has been cited as evidence of unpredictability of the claimed invention. The method employed by Hsiao lacks critical elements of the claimed invention because no correlation is made between $p21^{ras}$ function and $p21^{ras}$ level. To make such a correlation, Hsiao would need to isolate individual cell lines and characterize the level of $p21^{ras}$ in those cell lines. However, Hsiao did not isolate any individual cell lines or characterize the level of p21 present in any cell lines, much less correlate the level of $p21^{ras}$ with any function or phenotype of the cell line. Hsiao neither identifies, nor makes use of a "graded cellular response" or any other responsive change in a phenotypic characteristic. Hsiao's method does not rely on any association between POI level and phenotype that would enable one of ordinary skill to predictably identify compounds that directly activate or inhibit $p21^{ras}$.

16. In my opinion, one of ordinary skill in the art, having read Housey's specification, would not be misled by Hsiao's article into believing that any substance tested according to Hsiao's method was a direct activator or inhibitor of a POI. This is because Housey's method critically associates the level of the POI in a cell with a responsive phenotypic change. Hsiao does not.

17. Ledwith et al., Mol. Cell. Biol., 1990, Vol. 10, No. 4, pp. 1545-1555 (Ledwith) has also been cited as evidence of unpredictability. It was contended that if one of ordinary skill in the art used Housey's method to attempt to identify an inhibitor of $p21^{ras}$ and the test compound actually directly bound to and inhibited c-*fos*, the compound would erroneously be identified as an inhibitor of $p21^{ras}$. Ledwith has not made use of a "graded cellular response" or any other responsive change in a phenotypic characteristic. Accordingly, one of ordinary skill in the art, seeing the type of inhibition observed by Ledwith would not conclude that a compound causing such an effect was a direct inhibitor of $p21^{ras}$.

18. A responsive change in a phenotypic characteristic of a cell is a phenotypic characteristic that is responsive to inhibitors or activators of a given protein. A graded cellular response is an increase in the phenotypic change exhibited by the cell which becomes greater with increasing expression of the POI. Specification, page 12, lines 22-28. Ledwith has not established any correlation between the level of expression of $p21^{ras}$ and a responsive change in a phenotypic characteristic. Ledwith has only established a relationship between a protein in a cell that is not the POI (not the level of that protein) and the level of a compound that reduces the amount of that protein. Because a responsive change in a phenotypic characteristic of the $p21^{ras}$ overexpressing cells has not been defined, the effect of any compound (chemical, antisense RNA, or otherwise) cannot be evaluated according Housey's claimed method. To reach any

conclusion as to direct or indirect inhibition, Ledwith at least would need to evaluate terminal cell density as a function of $p21^{ras}$ level.

19. In my opinion, one of ordinary skill in the art, having read Housey's specification, would not be misled by Ledwith's article into believing that any substance tested according to Ledwith's method was a direct activator or inhibitor of a POI. This is because Housey's method critically associates the level of the POI in a cell with a responsive phenotypic change.

Date 4/5/06

James D. Griffin, M.D.

CURRICULUM VITAE

James D. Griffin, M.D.

Address: 156 Dean Road, Brookline, MA 02445

Date of Birth: March 17, 1948

Place of Birth: Cortland, New York

Education:

1970	A.B.	Brown University, Providence, RI
1972	M.M.S.	Brown University, Providence, RI
1974	M.D.	Harvard Medical School, Boston, MA

Postdoctoral Training:

Internship and Residencies:

1974 - 1975	Intern in Medicine, John Hopkins Hospital, Baltimore, MD
1975 - 1976	Resident in Medicine, John Hopkins Hospital, Baltimore, MD

Research and Clinical Fellowships:

1976 - 1977	Clinical and Research Fellow in Hematology, Massachusetts General Hospital, Boston, MA
1977 - 1979	Research Fellow in the Division of Tumor Virology, Dana-Farber Cancer Institute, Boston, MA
1979 - 1980	Clinical Fellow in Medical Oncology, Dana-Farber Cancer Institute, Boston, MA

Licensure and Certification:

1976	Massachusetts License No. 39416
1977	American Board of Internal Medicine, Certificate No. 59329
1978	Hematology Subspecialty, ABIM, Certificate No. 59329
1981	Medical Oncology Subspecialty, ABIM Certificate No. 59329

Academic Appointments:

1980 - 1981	Instructor in Medicine, Harvard Medical School, Boston, MA
1981 - 1985	Assistant Professor of Medicine, Harvard Medical School, Boston, MA
1985 - 1993	Associate Professor of Medicine, Harvard Medical School, Boston, MA
1993-	Professor of Medicine, Harvard Medical School, Boston, MA

Hospital Appointments:

1980 - 1981	Clinical Associate, Dana-Farber Cancer Institute
1980 - 1982	Junior Associate in Medicine, Brigham and Women's Hospital, Boston, MA
1981 - 1985	Assistant Physician, Dana-Farber Cancer Institute, Boston, MA
1982 -	Associate Physician, Brigham & Women's Hospital, Boston, MA
1983 -	Consultant Physician (Hematology/Oncology) Boston Veterans Administration Hospital
1985 –1993	Associate Physician, Dana-Farber Cancer Institute, Boston, MA
1993-	Attending Physician, Dana-Farber Cancer Institute, Boston, MA

Awards and Honors:

1969	Sigmi Xi
1974	Alpha Omega Alpha
1978 - 1977	Damon Runyon-Walter Winchell Fellow
1981 - 1982	Johanna C. Woods Foundation Fellow
1982 - 1983	Medical Foundation Fellow
1985 - 1990	Scholar, Leukemia Society of America
1989	American Society of Clinical Investigation
1993	Mario Baldini Visiting Professor of Hematology, New England Deaconess Hosptial, Boston, MA
1995-	External Advisory Board, Lombardi Cancer Center, Georgetown University Medical Center
1998-	External Advisory Board, Johns Hopkins Hospital Cancer Center
2000-	Principle Investigator, Specialized Center of Excellence
Award,	Leukemia and Lymphoma Society
2000-	National Board of Trustees, Leukemia and Lymphoma
Society	
2001	Dr. Anthony D. Cortese Award, Leukemia and Lymphoma
Society of	
	America
2001	Elected to Association of American Physicians
2001-	National Trustee, Leukemia and Lymphoma Society
2003-	External Advisory Board, Case Western Cancer Center

Major Committee Assignments:

Editorial:

1984 - 1988	Editorial Board, Blood
1984 - 1987	Editorial Board, Leukemia Research
1987 - 1990	Editorial Board, Experimental Hematology
1987 -	Editorial Board, Leukemia
1988 -	Associate Editor, Hematological Oncology
1988 - 1993	Associate Editor, Blood
1993 - 1998	Editor-in-Chief, Blood
1998-	Editorial Board, British Journal of Hematology
2000-	Editorial Board, Journal of Hematotherapy & Stem Cell Research

NIH:

1989 - 1993	NIH Study Section Member, Hematology 1
1990-	Ad hoc reviewer, NIH Hematology 1 Study Section and various PPG reviews
2000	Co-chair, Biology Roundtable, Progress Review Group, Leukemia, Lymphoma and Myeloma, National Cancer Institute

Dana Farber Cancer Institute:

1981 - 1989	Medical Oncology Fellowship Selection Committee
1982 - 1991	Transfusion Committee
1982 - 1984	Clinical Data Processing Committee
1983 - 1986	Bylaws Committee
1983 - 1990	Biomedical Research Support Grant Review Committee
1984 - 1986	Secretary, Medical Staff
1986 - 1987	President, Medical Staff
1990 - 1997	Scientific Review Committee
1995- 1997	Medical Executive Committee (Promotions)
1996- 1997	Research Promotions Committee
1997- 2002	Vice Chair for Research, Dept of Adult Oncology
1996- 1998	Executive Committee for Research
2001-	Executive Committee for Research
1996- 1998	Vice Chairman, Faculty Research Council
1997-	DFCI Institutional Promotions Committee
2001-	Promotions Committee, Dept of Adult Oncology
2001- 2002	Adult Oncology Executive Steering Committee
2002-	Chairman, Department of Medical Oncology, DFCI
2002-	Chief, Division of Medical Oncology, Brigham and Women's Hospital

Membership, Offices, and Committee Assignments in Professional Societies

1980 -	American Society of Hematology
1983 - 1986	Scientific Subcommittee on Leukocyte Physiology, ASH
1984 -	American Society of Clinical Oncology

1984 -	International Society of Experimental Hematology
1984 -	American Association of Immunologists
1984	Co-Director (Myeloid Section), Second International Workshop on Human Leukocyte Differentiation Antigens, Boston, MA, 17-20 September.
1985 - 1987	Scientific Subcommittee on Leukocyte Physiology, ASH
1987 - 1990	Scientific Subcommittee on Hematopoietic Growth Factors, ASH
1988 -	Public Relations Committee (Cytokines), ASCO
1989 -	American Society for Clinical Investigation
1991 -	American Society for Cancer Research
1993-1997	ASH Executive Committee
1993-1997	ASH Publication Committee
1993-1995	ASH Program Committee
1995	Chairman, Scientific Program, ASH
1998-2001	Chairman, Scientific Subcommittee on Hematopoietic Growth Factors, ASH
1998-	Scientific Committee, Leukemia Society of America
1998-2003	Advisory Board, American Society of Hematology
1999	Strategic Planning Committee, International Society of Hematology
1999-2003	Chairman, Publications Committee, International Society for Experimental Hematology
2000-	ASH Editor Selection Committee
2000-	ASCI Editor Selection Committee
2001- 2002	Chair, Experimental Hematology Editor Selection Committee, ISEH

Major Research Interests:

1. Regulation of hematopoiesis

2. Biology of myeloid leukemias

3. Leukemia oncogenes as targets for drug development

4. Notch receptor function

Teaching Experience:

1976 - 1977	Research and clinical seminars in Hematology, Massachusetts General Hospital
1977 - 1979	Taught course in Laboratory Hematology, University of Lowell
1978 - 1980	Supervision of a student laboratory research project on tumor virus proteins
1978 - 1980	Research seminars on tumor virus proteins and viral transformation.
1979 -	Supervision and didactic instruction of medical residents, interns, and medical students; lectures and seminars on Clinical Oncology, Dana Farber Cancer Institute

1980 -	Research seminars on myeloid leukemia antigens
1981 -	Consultation clinic, Dana-Farber Cancer Institute
1982 -	Lectures in Harvard Tumor Cell and Molecular Biology Course
1983 -	Lecturer in HMS Immunology 713.7/209 (Tumor Immunology)
1982, 1983	American Society of Hematology Educational Session, "Clinical Application of Immune Markers and Monoclonal Antibodies"
1984, 1986	Faculty, HMS Hybridomas in Biotechnology and Medicine Course
1985	Faculty, HMS Cancer Medicine Course
1987	Faculty, HMS Cancer Medicine Course
1988	Faculty, HMS Course, "Intensive review of Hematology and Hematologic Oncology."
1993-present	Faculty, HMS Cancer Medicine Course

Clinical and Hospital Service Responsibilities

1979 -	Medical Oncology Clinic, Dana-Farber Cancer Institute
1981 -	Attending Physician, Medical Oncology Service, Dana-Farber Cancer Institute
1981 -1993	Consultation Clinic, Dana-Farber Cancer Institute
1996-1997	Chief, Division of Hematologic Malignancies
1998- 2002	Director, Leukemia Program, Dana-Farber/Harvard Cancer Center
2002-	Chair, Department of Medical Oncology, DFCI, and Chief, Division of Medical Oncology, Brigham and Women's Hospital, Boston.

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Original Reports

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2. Coleman AW, Coleman JP, **Griffin JD**, Weltman JK, Chapman KM. Methylxanthine induced escalation: A propagated wave phenomenon observed in skeletal muscle developing in culture. Proc Natl Acad Sci USA 1972; 69:613-6.

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4. **Griffin JD**, Ellman L, Long JC, Dvorak AM. Development of a histiocytic medullary reticulosis-like syndrome in the course of acute lymphocytic leukemia. Am J Med 1978; 64:851-7.

5. **Griffin JD**, Aisenberg A, Long JC. Lymphocytic thymoma associated with T-cell lymphocytic leukemia. Am J Med 1978; 64:1075-80.

6. **Griffin JD**, Light S, Livingston DM. Measurements of the molecular size of the Simian virus 40 large T antigen. J Virol 1978; 27:218-26.

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9. **Griffin JD**, Spangler GJ, Livingston DM. Protein kinase activity associated with Simian virus 40 T antigen. Proc Natl Acad Sci USA 1979; 76:2610-4.

10. Spangler GJ, **Griffin JD**, Rubin H, Livingston DM. Identification and initial characterization of a new low molecular weight virus-encoded T antigen in a line of Simian virus 40-transformed cells. J Virol 1980; 36:488-98.

11. **Griffin JD**, Spangler GJ, Livingston DM. Enzymatic activities associated with the SV40 large T antigen. Cold Spring Harbor Symp; Quant Biol Vol XLIV: 1980; 113-22.

12. Bradley MK, **Griffin JD**, Livingston DM. Phosphotransferase activities associated with large T antigen. Cold Spring Harbor Conferences on Cell Proliferation. 1981; 8:1263-71.

13. Major PP, **Griffin JD**, Minden M, Kufe DW. A blast subline of the HL60 cell line. Leuk Res 1981; 5:429-30.

14. Todd RF, **Griffin JD**, Ritz J, Nadler LM, Abrams T, Schlossman SF. Expression of normal monocyte-macrophage differentiation antigens on HL60 promyelocytes undergoing differentiation induced by leukocyte-conditioned medium or phorbol diester. Leuk Res 1981; 5:491-5.

15. **Griffin JD**, Ritz J, Nadler LM, Schlossman SF. Expression of myeloid differentiation antigens on normal and malignant myeloid cells. J Clin Invest 1981; 68:932-41.

16. **Griffin JD**, Garnick MJ. Eye toxicity of cancer chemotherapy. Cancer 1981; 48:1539-49.

17. Nadler LM, Ritz J, **Griffin JD**, Todd RF, Reinherz EL, Schlossman SF. Diagnosis and treatment of human leukemias and lymphomas utilizing monoclonal antibodies. Prog Hematol 1981; 12:187-225.

18. Posner MR, Antoniou D, **Griffin JD**, Schlossman SF, Lazarus H. An enzyme-linked immunosorbent assay (ELISA) for the detection of monoclonal antibodies to cell surface antigens on viable cells. J Immunol Methods 1982; 48:23-31.

19. Bradley MK, **Griffin JD**, Livingston DM. Oligomerization and nucleotide binding properties of the SV40 large T antigen. Cell 1982; 28:125-34.

20. **Griffin JD**, Beveridge RP, Schlossman SF. Isolation of myeloid progenitor cells from peripheral blood of chronic myelogenous leukemia patients. Blood 1982; 60:30-7.

21. **Griffin JD**, Major PP, Monroe D, Kufe D. Induction of differentiation of human myeloid leukemia cells by inhibitors of DNA synthesis. Exp Hematol 1982; 10:774-81.

22. **Griffin JD**, Todd RF, Ritz J, Nadler LM, Canellos GP, Rosenthal DS, Gallivan MEV, Beveridge RP, Weinstein HJ, Karp D, Schlossman SF. Differentiation patterns in the blastic phase of chronic myeloid leukemia. Blood 1983; 61:85-91.

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57. **Griffin JD**, Maguire ME, Mayer RJ. Amsacrine in refractory acute leukemia. Cancer Treat Reports 1985; 787-789.

58. Biondi A, Roach JA, **Griffin JD**, Todd RF. Mb1, a plasma membrane antigen selectively expressed by U937 cells. Blood 1985; 66:135-42.

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